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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/417,226 10/13/99 SUNDREHAGEN

E REF/SUNDREHA

EXAMINER

HM12/0214

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ALEXANDRIA VA 22314-1176

HINES, J
ART UNIT

PAPER NUMBER

1645
DATE MAILED:

02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.
09/417,226

Applicant(s)
Sundrehagen et al.

Examiner
Ja-Na Hines

Group Art Unit
1645



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires 4 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Oct 10, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

- ☐ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☐ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: None

Claims objected to: None

Claims rejected: 1, 3-7, 9-12, 16-20, 24-33, 35, 36, 42-44, and 47-50

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Other

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ADVISORY ACTION

Amendment Entry

1. The amendment filed January 29, 2001 has been entered. Claims 1 and 4 have been amended. Claims 1, 3-7, 9-12, 16-20, 24-33, 35-36, 42-44, 47-50 are pending.

Information Disclosure Statement

2. The listing of references in the newly entered information disclosure statement is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office. The articles only contained an abstract, therefore only the abstract was reviewed.

Claim Objections

3. Claims 1, 3-7, 9-12, 16-20, 24-33, 35-36, 42-44, 47-50 are objected to because of the informalities. This rejection is withdrawn in view of applicants amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments.

Response to Arguments

Applicant's arguments filed January 29, 2001 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5-7, 10, 12, 16-20, 26 and 42-44, 47-48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLean et al., in view of Houts. McLean et al., teaches several monoclonal antibodies to transcobalamin II (TCII) is maintained. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.

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Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill is required to adjust the concentration of cobalamin in the sample. Therefore, it would have been obvious at the time of applicants invention to use the monoclonal antibodies to transcobalamin II, both apo- and holo-TCII, in a competitive sandwich ELISA assay on a solid support as taught by Houts, in the method of McLean, because Houts teaches a modified method of assaying TCII or any cobalamin analogues using samples from human plasma or serum, where a centrifuge step is performed and cyanocobalamin in either a direct or indirect assay can be assayed with any one of a variety of detectable signals can indicate presence using immobilized and non-immobilized ligands.

6. Claims 9, 11, 24-25 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLean et al., in view of Houts and further in view of Herbert is maintained. Applicants argue that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. No more than routine skill is involved in adjusting the amount of a component of a claimed process as stated in claims 3, 25 and 35-36. Neither changes in concentrations nor determining optimum concentrations which are suitable for materials have not been held to involve patentable inventions. Therefore one skilled in the art would have expected a

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reasonable level of success in using an assay to include the dissociation of cobalamin/ vitamin B₁₂ or analogs by changing the temperature or pH as taught by Herbert with the assay method for the determination of TCII bound cobalamin sample comprising contacting a sample body fluid with an immobilized specific binding ligand like a monoclonal antibody specific for TCII or holo-TCII, separating the bound fraction from the unbound fraction and measuring the amount of holo-TCII or TCII bound cobalamin obtained as taught by McLean et al., in view of Houts because Herbert teaches that this method is known in the art.

7. Claims 4 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLean et al., in view of Houts in further view of Allen et al., (US Patent 5,374,560) is maintained.

Applicants argument is that there is no suggestion to combine the references. In this case, no more than routine skill would have been required to use automation as taught by Allen et al., in the assay of McLean et al., and Houts, because Allen et al., shows it to be conventional and well known to automate assays to detect cobalamin. Furthermore, it has been held that broadly providing a mechanical or automatic assay to replace manual activity which has accomplished the same results involves only routine skill in the art (In re Venner, 120 USPQ 192).

8. Claims 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLean et al., in view of Houts in further view of Hoyle et al is maintained. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that

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obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious at the time of applicants invention to have use the antibodies of Hoyle et al., in the method of McLean et al., and Houts because the high affinity constants of the antibodies of Hoyle et al., which provide for a more sensitive assay.

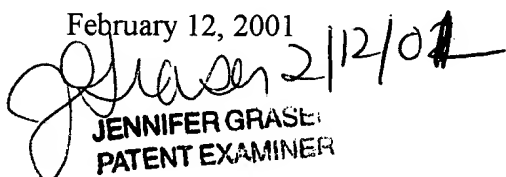
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

February 12, 2001

 2/12/01
JENNIFER GRASE
PATENT EXAMINER